K011210

AUG 1 5 2001

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Mrs. Julie A. Beaumont
Group Regulatory Affairs Technician
Willy Rüsch AG Group
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-6179
E-Mail: jbeaumont@tfx.com

Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Tube Tracheostomy and Tube Cuff

Common Name: Percutaneous Tracheostomy Kit

Proprietary Name: PercuQuick® Set

3. Identification of the legally marketed device to which the submitter claims equivalence.

The PercuQuick® Set is substantially equivalent to the SIMS/Portex, Per-Fit™ Percutaneou8s Dilational Tracheostomy Kit K936133.

4. Description of the Device.

The PercuQuick® Set consists of the following components:

Packaging 1:

- 7 dilators of different size, those marked 7, 8 and 9mm being intended for the insertion of the appropriate tracheostomy cannulas. For improved

lubrification their tips have been coated with a Hydrogel coating.

- A yellow guiding catheter with a safety stop for easier insertion of the dilators over the guide wire

Packing 2:

- 1 guide wire with a flexible J-tip and flexible straight end with lockable insertion aid
- 1 guide wire introduction needle to insert the guide wire into the trachea
- 1 10cc Luer syringe
- 1 size 10 scalpel
- 1 dilator with hand grip hub (first step) for initial dilation

Packaging 3:

- 1 PercuQuick® tracheostomy cannula with adjustable neck plate, bonded 15-mm standard connector and high-volume low-pressure cuff

See Attachment 1

5. Intended Use of the Device.

The Rüsch PercuQuick® Set for Percutaneous Dilation Tracheostomy is used to create a percutaneous dilational tracheostomy using dilators, guide catheter, and wire components of this product, and to provide a conduit for ventilation through the tracheostomy using the tracheostomy tube included in the kit.

6. Summary of Technological Characteristics.

The Rüsch PercuQuick® Set for Percutaneous Dilation Tracheostomy has the same technological characteristics as the SIMS/Portex Per-Fit Percutaneous Dilational Tracheostomy Kit

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mrs. Julie A. Beaumont
Rüsch International
Tall Pines Park
50 Plantation Drive
Jaffrey, NH 03452

Re: K011210
PercuQuick® Set
Regulation Number: 868.5800
Regulatory Class: II (two)
Product Code: JOH
Dated: July 30, 2001
Received: August 2, 2001

Dear Mrs. Beaumont:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011210

Device Name: PercuQuick® Set

Indications for Use:

The Rüsch PercuQuick® Set for Percutaneous Dilation Tracheostomy is used to create a percutaneous dilational tracheostomy using dilators, guide catheter, and wire components of this product, and to provide a conduit for ventilation through the tracheostomy using the tracheostomy tube included in the kit.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011210